

MAY 21 2009

10 510(k) Summary

Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Stacey Bonnell Regulatory Affairs Specialist Telephone: 610-719-5895 Facsimile: 610-719-5102 Email: bonnell.stacey@synthes.com
Date Prepared:	February 27, 2009
Trade Name:	Synthes Synapse Transconnector
Common Name:	Posterior Cervical System
Classification:	21 CFR 888.3050 Appliance, Fixation, Spinal Interlaminar Class II; Orthopaedic and Rehabilitation Devices Panel Product Code: KWP
Predicate Device:	Synthes Synapse System (K072434 & K070573) Synthes Cervifix (K011969)
Device Description:	<p>The Synthes Synapse Transconnector is a top-loading transconnector placed on top of two mono-segmental variable axis screws to cover the exposed spinal cord following laminectomy. The Synthes Synapse Transconnector is designed to be a rigid link between longitudinal rods, and is compatible only with Synthes Synapse System.</p> <p>The Synthes Synapse Transconnector is a line extension to Synthes Synapse System, and a modification to the Synthes Cervifix transconnector.</p> <p>The implants are manufactured from Titanium Aluminum Niobium TAN (Ti-6Al-7Nb) ASTM F1295, the same as the predicate device.</p>
Intended Use / Indications for Use:	<p>Synthes Synapse System is indicated for the following: <i>Hooks, Plate/Rods, Plates, Rods and Screws</i> When intended to promote fusion of the cervical spine and occipitocervical junction (occiput-T3), the plate/rod, plates, rod, hook and screw (3.2 mm cortex) components of the Synthes Cervifix, Axon, OC Fusion and Synapse Systems are indicated for the following:</p> <ul style="list-style-type: none"> • Degenerative Disc Disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies) • Spondylolisthesis • Spinal Stenosis • Fracture/dislocation • Atlantoaxial fracture with instability • Occipitocervical dislocation • Revision of previous cervical spine surgery • Tumor <p>When used to treat these cervical and occipitocervical conditions, screws are limited to occipital fixation only.</p>

	<p><i>Hooks and Rods</i> The rod and hook components are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.</p> <p><i>Rods, Clamps, Screws, Nuts, Variable Axis Screws, Locking Screws, and Transverse Bars</i> The rods, clamps, screws, nuts, variable axis screws, locking screws, and transverse bars are intended to promote fusion following reduction of fracture/dislocation or trauma in the upper thoracic spine (T1-T3).</p> <p>The use of these screws (3.5 mm, 4.0 mm and 4.5 mm cancellous, and 3.5 mm and 4.2 mm cortex) is limited to placement in T1-T3 in treating thoracic conditions only. They are not intended to be placed in or treat conditions involving the cervical spine.</p> <p>The Synthes CerviFix, Axon, and Synapse Systems can also be linked to the Synthes Universal Spinal System using the 3.5 mm/6.0 mm parallel connectors from that system and via the CerviFix tapered rods using lamina hooks, transverse process hooks, pedicle hooks, 4.2 mm screws and the 5.0 mm/6.0 mm parallel connector.</p> <p>Warning: This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic (T4-T12), or lumbar spine.</p>
Comparison of the technological characteristics of the device to the predicate device:	The Synthes Synapse Transconnector is a result of design modifications to the predicate device. Synthes has established that it is substantially equivalent to the predicates in design, function, material, and intended use.
Performance Data (Nonclinical and/or Clinical)	<p><i>Non-Clinical Performance and Conclusions:</i> Bench testing results demonstrate that the Synthes Synapse System is substantially equivalent to the predicate device.</p> <p><i>Clinical Performance and Conclusions:</i> Clinical data and conclusions were not needed for this device.</p>



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 21 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Synthes Spine
% Ms. Stacey Bonnell
Regulatory Affairs Specialist
1302 Wrights Lane East
West Chester, Pennsylvania 19380

Re: K090549

Trade/Device Name: Synthes Synapse System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminar fixation orthosis
Regulatory Class: II
Product Code: KWP
Dated: April 20, 2009
Received: April 21, 2009

Dear Ms. Bonnell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

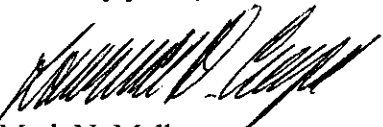
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

FOR 
Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

9 Indications for Use Statement

510(k) Number: K 090549
(if known)

Device Name: Synthes Synapse

Hooks, Plate/Rods, Plates, Rods and Screws

When intended to promote fusion of the cervical spine and occipitocervical junction (occiput-T3), the plate/rod, plates, rod, hook and screw (3.2 mm cortex) components of the Synthes Cervifix, Axon, OC Fusion and Synapse Systems are indicated for the following:

- Degenerative Disc Disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spinal Stenosis
- Fracture/dislocation
- Atlantoaxial fracture with instability
- Occipitocervical dislocation
- Revision of previous cervical spine surgery
- Tumor

When used to treat these cervical and occipitocervical conditions, screws are limited to occipital fixation only.

Hooks and Rods

The rod and hook components are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

Rods, Clamps, Screws, Nuts, Variable Axis Screws, Locking Screws, & Transverse Bars

The rods, clamps, screws, nuts, variable axis screws, locking screws, and transverse bars are intended to promote fusion following reduction of fracture/dislocation or trauma in the upper thoracic spine (T1-T3).

The use of these screws (3.5 mm, 4.0 mm and 4.5 mm cancellous, and 3.5 mm and 4.2 mm cortex) is limited to placement in T1-T3 in treating thoracic conditions only. They are not intended to be placed in or treat conditions involving the cervical spine.

The Synthes CerviFix, Axon, and Synapse Systems can also be linked to the Synthes Universal Spinal System using the 3.5 mm/6.0 mm parallel connectors from that system and via the CerviFix tapered rods using lamina hooks, transverse

process hooks, pedicle hooks, 4.2 mm screws and the 5.0 mm/6.0 mm parallel connector.

Warning: This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic (T4-T12), or lumbar spine.


Prescription Use **X**
(21 CFR 801 Subpart D)

AND / OR

Over-the-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


for (Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090549